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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,207	01/04/2005	Tadafumi Tamura	4093-6	7702
23117 7590 05/13/2008 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
EXAMINER				
WEN, SHARON X				
ART UNIT		PAPER NUMBER		
1644				
MAIL DATE		DELIVERY MODE		
05/13/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,207

Applicant(s)

TAMURA ET AL.

Examiner

SHARON WEN

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 4, 7, 8, 12 and 17-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 10, 16 and 49-51 is/are rejected.
- 7) ☒ Claim(s) 11, 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments filed 02/19/2008 have been entered.

Claims 1-51 are pending.

Claims 4, 7, 8, 12 and 17-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic claim.

Claims 1-3, 5-6, 9-11, 13-16 and 49-51 are currently under examination as they read on a method of treating arthritis comprising administering an antibody which specifically binds to FGF-8.

3. This Action will be in response to Applicant's Arguments/Remarks, filed 02/19/2008.

The rejections of record can be found in the previous Office Action, mailed 10/18/2007.

Priority

4. Applicant's amendment to the first line of the specification, filed 06/28/2004, for updating the priority claim is acknowledged.

Claim Rejections - 35 USC § 112 second paragraph

5. The previous rejection under 35 USC 112 second paragraph has been withdrawn in view of applicant's amendment, filed 02/19/2008.

Claim Rejections - 35 USC § 112 first paragraph

6. The previous rejections under 35 USC 112 first paragraph has been withdrawn in view of applicant's amendment to the claims and assurance provided for the biological deposit, filed 02/19/2008.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3, 5-6, 9-10, 16 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baird et al. (U.S. Patent 6,037,329) in view of Hanai et al. (U.S. Patent 5,952,472) and Owen et al. (*Journal of Immunological Methods*, 1994, 168:149-165).

Applicant's arguments, filed 02/19/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to Applicant's argument that the Baird reference teaches away the method of using antibody, Examiner points out that the teaching on antibody by Baird is in the context of immunotoxins in general (see column 1, lines 31-45). The reference does not teach using anti-FGF-8 antibody specifically is in anyway disadvantageous. Furthermore, the Hanai reference specifically teaches using the anti-FGF-8 antibody for therapeutic purposes (see e.g., Abstract and Background of the Inventions).

In response to Applicant's argument that the Baird reference does not teach or suggest treating arthritis and that Hanai does not cure the deficiencies of Baird, the following is noted.

It is undisputed that Baird et al. teach using an inhibitor of FGF-8 for therapeutic purposes (see, e.g., column 25 first full paragraph). Baird et al. also teach that members of the FGF family mediated pathological conditions such as arthritis (see column 10, last paragraph). Given that the members of the FGF family is well-defined by the state of the art and described by Baird (see column 10, second to last paragraph), it would have been obvious to try by one of skilled in the art at the time of the invention was made by choosing from the finite number of the members of the FGF family. Especially given the teaching by Hanai on using an anti-FGF-8 antibody as an

inhibitor of FGF-8 for therapeutic purposes, one of ordinary skill in the art would have been prompted to use the same antibody for treating one of the described pathological conditions mediated by FGF family as taught by Baird.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been persuasive.

This rejection is **maintained**.

Allowable Subject Matter

9. Claims 11 and 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1644

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./

Examiner, Art Unit 1644

May 1, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner

Art Unit 1644